

Application No.: 09/529,217

Docket No.: 21029-00196-US

Remarks

Reconsideration of claims 1-30 is respectfully requested. Claims 1, 7, 9, 11-13, 15, 17, 20-23 and 25 were amended. Claim 1 was amended to include in-part the limitations of previously pending claim 13, and to clarify that a denaturing agent is added to a previously washed sample to extract the specific probes from the probe-target complex.

Applicants respectfully request that the rejection of claims 20-23 and 25 under 35 U.S.C. §112, second paragraph be withdrawn. Applicants have amended the claims as suggested by the Examiner. In claim 25 the term "about", a commonly used term in the patent context, was added and the objected language removed. As the Examiner would agree, claim 25 recites an approximate value for given concentrations of denaturing agent, Tris-HCl and salt, within the values recited in claim 11. In all cases the recited values lie approximately at the halfway point within the broad range. As a result, one of skilled in the art would undoubtedly recognize the range of values defined by the term "about" presented in claim 25.

With respect to rejected claim 29, Applicants respectfully request that the rejection be withdrawn. There does not appear to be proper antecedent basis with respect to the term "said fixation solution".

The rejection of claims 1-12, 16-18 and 24-29 under 35 U.S.C. 103(a) as being patentable over Mayrand (US 5,691,146) in view of Burton and Nuovo (US 5,538,871) and in further view of De Los Reyes and Mobarry is respectfully traversed with respect to the amended claims. As stated in the Office Action, both Mayrand and Burton, the primary and secondary references in the rejection, respectfully, disclose a process of what is commonly referred to as *in situ* PCR amplification. *In situ* PCR is concerned with the amplification of DNA to detect DNA with high sensitivity and is strictly a qualitative technique.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for "omitting essential steps or elements" is respectfully traversed with respect to amended claim 1. As amended, claim 1 clarifies that following the addition of at least one specific probe to a sample containing microorganisms, thereby forming a sample with a probe-target complex, the

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sample is washed to remove excess specific probes or non-specific probes, thereby providing a washed sample. The denaturing agent is then added to the washed sample, to extract the probes from the probe-target complex. As a result, the only probes present in the denatured washed sample are those probes that were once tightly bound to the target. The concentration of those probes are then measured using an analytical detector to provide a quantifiable value of the amount of probe-target complex that was present in the sample containing microorganisms following contact of this sample with at least one specific probe.

Claim 1 was amended to include in-part the limitations of objected claim 13. This amendment along with the other amendments made to claim 1 clarifies that Applicants' inventive technique is not a classic PCR technique. For one reason, the number of probes detected is substantially equal to the number of probes originally bound to the targets, that is, there is no amplification. The detection of the probes therefore corresponds to the amount of target in the original sample. Accordingly, Applicants respectfully request that the rejections be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21029-00196-US from which the undersigned is authorized to draw.

Dated: 10-2-03

Respectfully submitted,

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